



CASE ON/4-30811A

## FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 540157243US

Express Mail Label Number

May 15, 2006

Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT APPLICATION OF: Matthews, et al.

Art Unit: 1614

Examiner: B.Y.S. Kwon

APPLICATION NO: 09/930,3354

FILED: August 15, 2001

U.S. APPLICATION NO: 09/930,335

FOR: SPONTANEOUSLY DISPERSIBLE N-BENZOYL STAUROSPORINE

**COMPOSITIONS** 

**MS: Amendment** 

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 of the international application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicant wishes to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (617) 871-3216

Date: 15 May 06

Respectfully submitted,

Attorney for Applicant

Reg. No. 44,848

FORM PTO-1449 (REV. 7-85) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. 4-30811A APPLICATION NO. 09/930,335 APPLICANT

**FILING DATE** 

Group 1614

#### **U.S. PATENT DOCUMENTS**

| EXAMINER INITIAL |    | DOCUMENT NUMBER | DATE     | NAME             | CLASS | SUBCLASS | FILING DATE |
|------------------|----|-----------------|----------|------------------|-------|----------|-------------|
|                  | АА | 4,735,939       | 4/5/88   | McCoy et al.     | 514   | 211      |             |
|                  | АВ | 4,963,367       | 10/16/90 | Ecanow           | 424   | 485      |             |
|                  | AC | 5,093,330       | 3/3/92   | Caravatti et al. | 514   | 211      |             |
|                  | AD | 5,444,041       | 8/22/95  | Owen et al.      | 514   | 356      |             |
|                  | AE | 5,599,808       | 2/4/97   | Goldstein et al. | 514   | 211      |             |
|                  | AF | 5,639,474       | 6/17/97  | Woo              | 427   | 465      |             |
|                  | AG | 5,658,898       | 8/19/97  | Weder et al.     | 514   | 211      |             |
|                  | АН | 5,707,648       | 1/13/98  | Yiv              | 424   | 450      |             |
|                  | Al | 5,726,164       | 3/10/98  | Weder et al.     | 514   | 80       |             |
|                  | AJ | 5,736,542       | 4/7/98   | Henry et al.     | 514   | 211      |             |
|                  | AK | 5,932,243       | 8/3/99   | Fricker et al.   | 424   | 450      |             |
|                  | AL |                 |          |                  |       |          |             |

#### **FOREIGN PATENT DOCUMENTS**

|   |    | DOCUMENT NUMBER | DATE    | OFFICE  | CLASS | SUBCLASS | TRAN<br>YES | SLATION<br>NO |
|---|----|-----------------|---------|---------|-------|----------|-------------|---------------|
|   | АМ | EP 0 657 164 A  | 6/14/05 | Europe  |       |          |             |               |
|   | AN | WO 98 33512 A   | 8/6/98  | PCT     |       |          |             |               |
|   | AO | EP 0 733 358 A2 | 9/25/96 | Europe  |       | -        |             |               |
|   | AP | EP 0 711 556 A1 | 5/15/06 | Europe  |       |          |             |               |
| - | AQ | DE 44 18 115 A1 | 5/24/94 | Germany |       |          |             |               |

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| AR | Alkan et al. "Effects of a New Protein Kinase C Inhibitor CGP 41251 on T Cell Functions: Inhibition of Activation, Growth, and Target Cell Killing," Cellular Immunology, Vol. 150, pp. 137-148 (1993)   |
|----|--|
| AS | Andrejauskas-Buchdunger et al. "Differential Inhibition of the Epidermal Growth Factor-, Platelet-deirved Growth Factor-, and Protein Kinase C-mediated Signal Transduction Pathways by the Staurosporine Derivative CGP 41251," Cancer Research, Vol. 52, pp. |
| AT | Begemann, Martin et al. "Inhibition of the Growth of Glioblastomas by CGP 41251, an Inhibitor of Protein Kinase C, and by a Phorbol Ester Tumor Promoter," Clinical Cancer Research, Vol. 2, pp. 1017-1030 (1996)  |

**EXAMINER** 

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

## **INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

ATTY. DOCKET NO. 4-30811A APPLICATION NO. 09/930,335 APPLICANT

**FILING DATE** 

Group 1614

| U.S. PATENT DOCUMENTS |                            |   |   |   |   |  |  |                          |
|-----------------------|----------------------------|---|---|---|---|--|--|--------------------------|
| EXAMINER<br>INITIAL   |                            | DOCUMENT NUMBER   | DATE  | NAME  | CLASS   | SUBCLASS   | FILI                                   | NG DATE                  |
|                       | ВА                         |   | <del></del> -   |   |   |  |  |                          |
| -                     | вв                         |   | _   |   |   |  |  |                          |
|                       | вс                         |   |   |   |   |  |  |                          |
|                       | BD                         |   |   |   |   |  |  |                          |
|                       | BE                         |   |   |   |   |  |  |                          |
|                       | BF                         |   |   |   |   |  |  |                          |
|                       | BG                         |   |   |   |   |  |  |                          |
|                       | вн                         |   |   |   |   |  |  |                          |
|                       | ВІ                         |   |   |   |   |  |  |                          |
|                       | BJ                         |   |   |   |   |  |  |                          |
|                       | вк                         |   |   |   |   |  |  |                          |
|                       | BL                         |   |   |   |   |  |  |                          |
|                       |                            |   | FOREIG  | N PATENT DOCUMENTS  |   |  |  |                          |
|                       |                            |   |   |   |   |  |  |                          |
|                       |                            | DOCUMENT NUMBER   | DATE  | OFFICE  | CLASS   | SUBCLASS   | TRAN<br>YES                            | SLATION<br>NO            |
|                       | ВМ                         | GB 2 308 545 A  | 7/2/97  | OFFICE Great Britain  | CLASS   | SUBCLASS   |  |                          |
|                       | BM<br>BN                   |   |   |   | CLASS   | SUBCLASS   | YES                                    |                          |
|                       |                            | GB 2 308 545 A  | 7/2/97  | Great Britain   | CLASS   | SUBCLASS   | YES                                    | NO                       |
|                       | BN                         | GB 2 308 545 A<br>WO 95/14037   | 7/2/97<br>5/26/95   | Great Britain PCT   | CLASS   | SUBCLASS   | YES                                    | NO                       |
|                       | BN<br>BO                   | GB 2 308 545 A<br>WO 95/14037<br>WO 98/15255  | 7/2/97<br>5/26/95<br>4/16/98  | Great Britain PCT PCT   | CLASS   | SUBCLASS   | YES                                    | NO                       |
|                       | BN<br>BO<br>BP             | GB 2 308 545 A<br>WO 95/14037<br>WO 98/15255<br>WO 98/18321   | 7/2/97<br>5/26/95<br>4/16/98<br>5/7/98<br>4/2/98<br>7/16/98   | Great Britain PCT PCT   |   |  | YES                                    | NO                       |
|                       | BN<br>BO<br>BP<br>BQ       | GB 2 308 545 A WO 95/14037 WO 98/15255 WO 98/18321 WO 98/13032 WO 98/30204 OTHER DOC Begemann, Martin. "T   | 7/2/97 5/26/95 4/16/98 5/7/98 4/2/98 7/16/98 UMENTS ( reatment of and CDK2 K                                      | Great Britain  PCT  PCT  PCT  PCT  PCT  Including Author, Title, Date, Pertine  Human Glioblastoma Cells with inase Activity and Increase Rac                                     | nt pages, E   | itc.)  | YES                                    | NO                       |
|                       | BN<br>BO<br>BP<br>BQ<br>BR | GB 2 308 545 A  WO 95/14037  WO 98/15255  WO 98/18321  WO 98/13032  WO 98/30204  OTHER DOC  Begemann, Martin. "T 41251 Inhibits CDC2 Research. Vol 18. pp. Blobe, Gerard, et al.        | 7/2/97 5/26/95 4/16/98 5/7/98 4/2/98 7/16/98 UMENTS ( reatment of and CDK2 K 2275-2282                            | Great Britain  PCT  PCT  PCT  PCT  PCT  Including Author, Title, Date, Pertine  Human Glioblastoma Cells with inase Activity and Increase Rac                                     | nt pages, E<br>the Stau<br>diation Se                           | rosporine Densitivity," Ant                            | TES  TES  TES  TES  TES  TES  TES  TES | NO CGP                   |
|                       | BN<br>BO<br>BP<br>BQ<br>BR | GB 2 308 545 A WO 95/14037 WO 98/15255 WO 98/18321 WO 98/30204 OTHER DOC Begemann, Martin. "T 41251 Inhibits CDC2 a Research. Vol 18. pp. Blobe, Gerard, et al. Multidrug-resistant Moc | 7/2/97 5/26/95 4/16/98 5/7/98 4/2/98 7/16/98 UMENTS ( freatment of and CDK2 K 2275-2282 "Selective R CF-7 Cells," | Great Britain  PCT  PCT  PCT  PCT  Including Author, Title, Date, Pertine  Human Glioblastoma Cells with inase Activity and Increase Rac (1998)  egulation of Expression of Prote | nt pages, E<br>the Stau<br>diation Se<br>sin Kinase<br>Vol. 268 | rosporine Densitivity," Ante C (PKC) Iso, No. 1, pp. 6 | rivative                               | NO  CGP r es in 4 (1993) |

<sup>\*</sup>EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. 4-30811A APPLICATION NO. 09/930,335 APPLICANT

FILING DATE

Group 1614

| EXAMINER<br>INITIAL | OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.) |   |  |  |  |  |  |  |
|---------------------|--|---|--|--|--|--|--|--|
|                     | DA   | Chung, Denise et al. "Evidence that the ras oncogene-encosed p21 protein induces oocyte maturation via activation of protein kinase C," Proc. Natl. Acad. Sci. USA, Vol 89, pp. 1993-1996. (1992)   |  |  |  |  |  |  |
|                     | DB   | Dietel, Manfred. "Second International Symposium on Cytostatic Drug Resistance," Cancer Research, Vol. 53, pp.2683-2688 (1993)  |  |  |  |  |  |  |
|                     | DC   | Erikson, Raymond L. "Structure, Expression, and Regulation of Protein Kinases Involved in the Phosphorylation of Ribosomal Protein S6," Journal of Biological Chemistry, Vol. 266, No. 10. pp. 6007-6010 (1991)   |  |  |  |  |  |  |
|                     | DD   | Fuse, E. et al. "Unpredicated Clinical Pharmacology of UCN-01 Caused by Specific Binding to Human alpha1-Acid Glycoprotein," Cancer Research, Vol. 58, pp. 3248-3253, (1998)  |  |  |  |  |  |  |
|                     | DE   | Gottesman, Michael M. "How Cancer Cells Evade Chemotherapy: Sixteenth Richard and Hinda Rosenthal Foundation Award Lecture," Cancer Research 53, pp. 747-754 (1993)   |  |  |  |  |  |  |
|                     | DF   | Hill, D.L, et al. "Binding of UCN-01 to Plasma Proteins of Humans, Rats and Dogs," Proceeding of the Amer. Assoc. for Cancer Research, Vol. 39, p. 364 (1998)   |  |  |  |  |  |  |
|                     | DG   | Ikegami Y.et al. "Effects of the New Selective Protein Kinase C Inhibitor 4'-N-Benzoyl Staurosporine on Cell Cycle Distribution and Growth Inhibition in Human Small Lung Cancer Cells", Jpn. J. Pharmacol. Vol. 70, pp. 65-72 (1996)                         |  |  |  |  |  |  |
|                     | DH   | Ikegami, Yuri et al. "Antitumor Effect of CGP41251, a New Selective Protein Kinase C Inhibitor, on Human Non-Small Cell Lung Cancer Cells," Jpn. J. Pharmacol., Vol. 70. pp. 65-72 (1996)   |  |  |  |  |  |  |
| •                   | DI   | Killion J.J. et al. "The Antitumor Activity of Doxorubicin against drug-resistant murine carcinoma is enhanced by oral administration of synthetic staurosporine analogue," Oncology Research, Vol. 7, No. 9, pp. 453-459 (1995)                              |  |  |  |  |  |  |
|                     | DJ   | Ludescher Ch. et al. "Decreased Potency of MDR-modulators under serum conditions determined by a functional assay," Brit. J. of Haematology, Vol. 91, pp. 652-657 (1995)  |  |  |  |  |  |  |
|                     | DK   | Mack, P.C. et al. "7-hydroxystaurosporine (UCN-01) plus cisplatin (CDPP): molecular mechanisms of does-,time- and sequence-dependent potentiation in non-small cell lung carcinoma (NSCLC)," Clincial Pharmacology, Proceeding of Asco, Vol. 16. pp. 212a. (1 |  |  |  |  |  |  |
|                     | DL   | Marte, B.M. et al. "Protein Kinase C and Mammary Cell Differentiation: Involvement of Protein Kinase C alpha in the Induction of Beta-Casein Expression," Cell Growth & Differentiation, Vol. 5, pp. 239-247 (1994)   |  |  |  |  |  |  |
|                     | DM   | Matter A., et al. "Pharmacological Approach to growth regulation of breast cancer cells", pp. 227-241   |  |  |  |  |  |  |
|                     | DN   | Meggio, Flavio, et al. "Different susceptibility of protein kinases to staurosporine inhibition," Eur. J. Biochem, Vol. 234, pp. 317-322. (1995)  |  |  |  |  |  |  |
| EXAMINER            | <u> </u>   | DATE CONSIDERED   |  |  |  |  |  |  |

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

# **INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

ATTY. DOCKET NO. 4-30811A APPLICATION NO. 09/930,335 APPLICANT

**FILING DATE** 

Group 1614

| EXAMINER<br>INITIAL | OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.) |   |  |  |  |  |  |
|---------------------|--|---|--|--|--|--|--|
|                     | DA   | Meyer, Th.,et al. "A Derivative of Staurosporine (CGP 41 251) Shows Selectivity For Protein Kinase C Inhibition and InVitro Anti-proliferative as well as In Vivo Anti-tumor Activity," Int. J. Cancer, vol. 43, pp. 851-856 (1989)   |  |  |  |  |  |
|                     | DB   | Miyamoto, Ken-ichi. "Inhibition of Multidrug Resistance by a New Staurosporine Derivative, NA-382, in Vitro and in Vivo," Cancer Research. Vol. 53. pp. 1555-1559. (April 1, 1993)  |  |  |  |  |  |
|                     | DC   | Pastan et al. "Multidrug Resistance," Annu. Rev. Med., Vol. 42, pp. 277-86 (1991)   |  |  |  |  |  |
|                     | DD   | Sampson, K.E. et al. "Staurosporine reduces P-glycoprotein expression and modulates multidrug resistance," Cancer Letters, Vol. 68, pp. 7-14 (1993)   |  |  |  |  |  |
|                     | DE   | Sato, Wakao et al. "Staurosporine, a potent inhibitor of C-kinase, enhances drug accumulation in multidrug-resistant cells," Biochemical and Biophysical Research Communications, Vol. 173, No. 3 (1990)  |  |  |  |  |  |
|                     | DF   | Sedlak, J. et al. "Effects of protein kinase C inhibitor, staurosporine derivative CGP 41 251, on cell cycle, DNA synthesis and drug uptake in neoplastic cell lines," Anti-Cancer Drugs Vol. 6, pp. 70-76 (1995)   |  |  |  |  |  |
|                     | DG   | Simon, Sanford et al. "Cell biological mechanisms of multidrug resistance in tumors," Proc. Natl. Acad. Sci, USA, Vol. 91, pp. 3497-3504 (1994)   |  |  |  |  |  |
|                     | DH   | Susa, Mira et al. "Inhibition or Down-regulation of Protein Kinase C Attenuates Late Phase p70s6k Activation Induced by Epidermal Growth Factor but Not by Platelet-derived Growth Factor or Insulin," Journal of Biological Chemistry, Vol. 267, No. 10. pp.                           |  |  |  |  |  |
|                     | DI   | Utz, I. et al. "The Protein Kinase C Inhibitor CGP 41251, A Staurosporine Derivative with Antitumor Activity, Reverses Multidrug Resistance," Int. J. Cancer, Vol. 57, pp. 104-110 (1994)   |  |  |  |  |  |
|                     | DJ   | Utz, Irene. "Reversal of Multridrug Resistance by the Staurosporine Derivatives CGP 41251 and CGP 42700," Int. J. Cancer. Vol. 77 pp.64-69 (1998)   |  |  |  |  |  |
|                     | DK   | Van Kalken, et al. "Multidrug Resistance form the Clinical Point of View" Eur. J Cancer, Vol. 27, No. 11. pp. 1481-1486. (1991)   |  |  |  |  |  |
|                     | DL   | Schwarz, et al. "Effect on the partition equilibrium of various drugs by the formation of mixed bile salt/phosphatidylcholine/fatty acid micelles A characterization by micellar affinity capillary electrophoresis Part IV,": Journal of Chromatography A, Vol. 809 pp. 219-229 (1998) |  |  |  |  |  |
|                     | DM   | Borkovec, Michal. "Phenommenological Theories of Globular Microemulsion," Advances in Colloiod and Interface Science. Vol. 37, pp. 195-217 (1992)   |  |  |  |  |  |
|                     | DN   | Beltran, Pedro et al. "Chemosensitization of Cancer Cells by the Staurosporine Derivative CGP 41251 in Association with Decreased P-Glycoprotein Phosphorylation," Biochemical Pharamcology Vol 53 pp. 245-247 (1997)   |  |  |  |  |  |
| EXAMINE             | R  | DATE CONSIDERED   |  |  |  |  |  |

<sup>\*</sup>EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.